83-196

No.

In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

MONSANTO COMPANY

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

JURISDICTIONAL STATEMENT

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QUESTIONS PRESENTED

1. Whether Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. (& Supp. V) 136a(c)(1)(D) (which permits applicants to cite and EPA to consider in support of subsequent applications by other companies, health and safety data that were submitted to the government in support of initial applications for pesticide registration), works an unconstitutional taking of property requiring issuance of injunctive relief.

2. Whether 7 U.S.C. (Supp. V) 136a(c)(2)(A) and 7 U.S.C. (& Supp. V) 136h of FIFRA, which require EPA to disclose publicly health and safety data submitted to the agency in support of a pesticide registration application, are beyond Congress's power and constitute an unconstitutional taking of property warranting injunctive relief.

3. Whether the constitutionality of the arbitration scheme established in 7 U.S.C. (Supp. V) 136a(c)(1)(D)(ii) (which provides that an original data submitter or an applicant who cited that data may initiate binding arbitration if the parties fail to agree on the amount of compensation) is ripe for review, and, if so, whether the arbitration provision denies due process or amounts to an unconstitutional delegation of judicial power.

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JURISDICTIONAL STATEMENT

OPINION BELOW

The opinion of the district court (App. A, *infra*, 1a-37a) is not reported.

JURISDICTION

The judgment of the district court (App. B, *infra*, 39a-40a) was entered on April 12, 1983. An amended judgment (App. C, *infra*, 41a-43a) was entered on May 9, 1983. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on May 10, 1983 (App. D, *infra*, 44a-46a). On July 1, 1983, Justice Blackmun extended the time for docketing the appeal to August 8, 1983. The

jurisdiction of this Court is invoked under 28 U.S.C. 1252.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (& Supp. V) 136 *et seq.* are reprinted in App. E, *infra*, 47a-57a.

STATEMENT

1. This appeal involves a challenge to the constitutionality of key provisions of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. (& Supp. V) 136 *et seq.* These provisions govern the Environmental Protection Agency's ("EPA") use of health and safety information submitted to it by an applicant seeking to register a pesticide. The provisions at issue permit EPA to consider, in support of subsequent applications by other companies, health and safety data that were submitted to the government by the initial applicant (the "data consideration" provisions) and require EPA to disclose certain health and safety data to qualifying members of the public (the "data disclosure" provisions). Thus, the only data that are affected in this case relate to health and safety; the case does not involve product formulas or manufacturing processes, which are protected from disclosure by other statutory provisions.

Pursuant to FIFRA, pesticide manufacturers normally must obtain a registration from EPA before any pesticide product may be sold in the United States.[1] A pesticide may be registered if its use will

[1] When EPA registers a pesticide product under FIFRA, it approves the composition and labeling for that product and

not cause unreasonable adverse effects to the environment (7 U.S.C. (Supp. V) 136a(c)(5)), or, in the case of products similar to those already registered, will not significantly increase the risk of such effects (7 U.S.C. (Supp. V) 136a(c)(7)). EPA's decision whether to register a particular pesticide product depends upon its evaluation of both the usefulness of the product and the dangers presented by its use to human, animal, or plant life. See 7 U.S.C. 136(bb) and 7 U.S.C. (Supp. V) 136a(c)(5)(C)-(D). To carry out its regulatory responsibilities, EPA and its predecessors have required manufacturers to submit a variety of test data in support of applications for registrations. These data define the risks and benefits of the product for which registration is sought, and generally include data on the chemical nature and structure of the pesticide, as well as test data concerning the potential dangers of the product.[2]

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allows that product to be sold for the approved labeling use. A label must contain: (1) general information such as the name of the manufacturer, and type of product and the registration number; (2) hazard statements; (3) directions for use; and (4) limitations on use (App. A, *infra*, 7a).

[2] The health and safety data required for registration consist of the following major types of studies: (1) acute toxicity studies, which define how poisonous the pesticide is when ingested, inhaled, or applied to the skin or eyes; (2) chronic toxicity studies, which are used to determine if chronic exposure to the pesticide will have any long-term health effects such as causing cancer or birth defects; (3) residue studies, which define the level of the pesticide and its degradation products which remain in the food; (4) environmental chemistry studies, which are used to determine how much of the pesticide and its degradation products remain in the environment after application; and (5) fish and wildlife studies, which define how toxic the pesticide is to fish and wildlife which may be exposed to the pesticide after application in the environment (App. A, *infra*, 17a). See 47 Fed. Reg. 53192-53221 (1982).

As originally enacted in 1947, FIFRA was silent on the question of public disclosure of submitted health and safety data and on the authority to consider such data in support of subsequent applications for the same or similar pesticide by other companies.[3] In 1972, Congress substantially revised FIFRA and for the first time addressed the issue of consideration and disclosure of submitted data. Federal Environmental Pesticide Control Act of 1972 (Pub. L. No. 92-516, 86 Stat. 973 *et seq.*) ("1972 Amendments"). A new Section 10 (86 Stat. 989) was added governing public disclosure of data submitted in support of applications for registration. This provision allowed applicants to designate portions of submitted data as "trade secrets or commercial or financial information" and it prohibited EPA from publicly disclosing any such information. In addition, Congress added a new Section 3(c)(1)(D) (86 Stat. 979) which provided that any "trade secret" data that could not be publicly disclosed under Section 10 could not be considered in support of another registration application, without the data-submitter's permission. All other data could be considered by EPA, but only if the later applicant offered the original data submitter compensation for

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[3] Under the original Act and until 1970, registrations were granted by the United States Department of Agriculture ("USDA"). In 1970, EPA assumed responsibility for registrations. 7 U.S.C. 136a. The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 did not prohibit USDA from considering relevant data supplied to it by one applicant to support the applications of other companies, and USDA did not require applicants to duplicate tests already in USDA's files. The Act also contained no prohibition against public disclosure of data submitted in support of a registration (including health and safety data). It did, however, specifically prohibit disclosure of product formulas (7 U.S.C. (1970 ed.) 135a(c)(4) and 135f(c)).

its use. The amount of compensation would be determined either through negotiation between the parties, or would be fixed by EPA, subject to judicial review (*ibid.*).

The 1972 Amendments, however, failed to define "trade secrets," and failed to specify an effective date. The latter question was resolved in 1975 when Congress amended Section 3(c)(1)(D) to provide that the consideration provisions applied only to data submitted on or after January 1, 1970. Pub. L. No. 94-140, 89 Stat. 751.[4] The definition of "trade secret" was left to the EPA Administrator and the courts.

EPA maintained that in the 1972 and 1975 Amendments Congress had intended to give trade secret protection to only a narrow range of data—principally statements of formulas and manufacturing processes. EPA thus concluded that the amendments did not protect health and safety data. Such data, therefore, could be disclosed to the public and could be considered by EPA in support of registration applications. In a series of lawsuits, data-submitting firms challenged EPA's interpretation and obtained several decisions holding that in 1972 Congress had intended the "trade secret" prohibition to apply to any data, including health and safety data, that met the expansive "trade secret" criteria specified in the

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[4] Section 3(c)(1)(D), as amended in 1975, was challenged by an original data submitter on the ground that Section 3(c)(1)(D) caused an unconstitutional taking of its property rights in the data it had submitted prior to January 1, 1970. This claim was rejected by a three-judge court, which held that Section 3(c)(1)(D) did not "take" any property rights. *Mobay Chemical Corp.* v. *Costle*, 12 E.R.C. 1572 (W.D. Mo. 1978). A direct appeal to this Court under 28 U.S.C. 1253 was dismissed on the ground that the three-judge court had been improperly convened. 439 U.S. 320 (1979).

Restatement of Torts § 757 (1939). *E.g., Chevron Chemical Co.* v. *Costle*, 443 F. Supp. 1024 (N.D. Cal. 1978); *Mobay Chemical Corp.* v. *Costle*, 447 F. Supp. 811 (W.D. Mo. 1978). As a result of these decisions, the "trade secret" prohibition in Section 10 operated to bar public access to much of the data on which EPA based its decisions to register pesticides; and the corresponding prohibition in Section 3(c)(1)(D) allowed data-submitters to prevent any other firm from obtaining registrations for products that were the same or substantially the same as previously registered products unless the second firm duplicated the data supporting the first registration or it was determined, after perhaps years of litigation, that particular items of data were not trade secrets. In part because of such "trade secret" controversies, "the process of registering new pesticides simply ground to a halt." *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104, 111 (3d Cir.), cert. denied, 452 U.S. 961 (1981).[5] See H.R. Rep. No. 95-663, 95th Cong., 1st Sess. 18 (1977), S. Rep. No. 95-334, 95th Cong., 1st Sess. 3 (1977).

Faced with this breakdown in the registration program, Congress, in the Federal Pesticide Act of 1978 ("1978 Amendments"), comprehensively revised the FIFRA data consideration and disclosure provisions, changing both Sections 3(c)(1)(D) and 10. The 1978 Amendments abolished the earlier prohibition (in Section 3(c)(1)(D)) on agency consideration of "trade secret" data because it had operated to discourage small potential competitors from entering the market by requiring them to duplicate health and safety tests for products already established as

[5] See generally Schulberg, *The Proposed FIFRA Amendments of 1977: Untangling the Knot of Pesticide Registration*, 2 Harv. Envtl. L. Rev. 342 (1977).

registrable by data that were contained in EPA's files but were rendered inaccessible by statute.[6] Congress was concerned that the FIFRA data requirements, in practice, acted as a de facto extension of patents beyond the statutory period of protection. See, *e.g.*, S. Rep. No. 95-334, 95th Cong., 1st Sess. 8, 30-31 (1977). In order to encourage competition and eliminate needless duplicative testing on pesticide chemicals already determined to be safe (see S. Rep. No. 95-334, *supra*, at 30, 31), Congress established a new and comprehensive registration scheme. The new scheme spreads the costs of developing health and safety data among all beneficiaries of the data while at the same time protecting innovation incentives through exclusive use and compensation provisions (*ibid.*). Under the 1978 Amendments, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. Section 3(c)(1)(D)(i), 7 U.S.C. (Supp. V) 136a(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission, if the applicant offers to compensate the original submitter. Section 3(c)(1)(D)(ii), 7 U.S.C. (Supp. V) 136a(c)(1)(D)(ii). In these instances, the data are not

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[6] Most of the pesticide products for which registration is sought contain active ingredients that are also contained in previously registered products. Because the first registrant(s) of products containing a particular active ingredient normally will have supplied substantial amounts of health and safety data, EPA's files contain much data relevant to subsequent decisions whether to register other products containing the same ingredient. As the district court found, most of the testing and research is done by a few, relatively large firms, of which Monsanto is one (App. A, *infra*, 4a).

disclosed to the later applicant but are viewed only by EPA personnel. The later applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings.[7] Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. Section 3(c)(1)(D)(iii), 7 U.S.C. (Supp. V) 136a(c)(1)(D)(iii).

The 1978 Amendments also added a new provision, Section 10(d) (7 U.S.C. (Supp. V) 136h(d)), that provides for public disclosure of all health and safety data.[8] This provision was designed to enable members of the public to assess for themselves the hazards posed by pesticide products and to participate in and evaluate EPA's registration decisions.[9] See, *e.g.*, H.R.

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[7] The decision of the arbitrator may be overturned for "fraud, misrepresentation, or other misconduct." 7 U.S.C. (Supp. V) 136a(c)(1)(D)(ii).

[8] Under Section 10(d)(1), 7 U.S.C. (Supp. V) 136h(d)(1), EPA must, on request, disclose to qualified requestors "[a]ll information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation, and fate in the environment, and metabolism."

[9] Because of the health and safety significance of the data submitted in support of an application for a pesticide registration, EPA often receives requests for access to this infor-

Rep. No. 95-663, 95th Cong., 1st Sess. 18 (1977); 123 Cong. Rec. 13097 (daily ed. July 29, 1977) (remarks of Sen. Kennedy). The same section, however, prohibits EPA from disclosing information that would reveal "manufacturing or quality control processes" or certain details pertaining to "deliberately added" inert ingredients unless "the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment." In addition, Section 10(g) generally prohibits EPA from disclosing data to foreign or multinational pesticide producers, unless the original submitter consents. Section 10(g), 7 U.S.C. (Supp. V) 136h(g).

2. In its complaint in the United States District Court for the Eastern District of Missouri, Monsanto sought injunctive and declaratory relief from the operation of the data consideration provisions of Section 3(c)(1)(D), 7 U.S.C. (Supp. V) 136a(c)(1)(D), and the disclosure provisions of Section 10, 7 U.S.C. (Supp. V) 136h and related Section 3(c)(2)(A), 7 U.S.C. (Supp. V) 136a(c)(2)(A). Monsanto alleged

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mation from environmental organizations interested in protecting man and the environment from the adverse effects of these pesticide chemicals, from farm worker unions that serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and from union groups that represent the chemical workers who manufacture pesticides. Moreover, FIFRA specifically provides for public participation in EPA's decision-making process. Members of the public may petition EPA to take regulatory action. See 7 U.S.C. (& Supp. V) 136a. They may comment in rule-making proceedings and on other regulatory actions. See, *e.g.*, 7 U.S.C. 136a(b). And, they may petition for the commencement of, and participate in, administrative hearings to cancel or deny a pesticide registration. See, *e.g.*, 7 U.S.C. 136d(d); 40 C.F.R. 164.31.

that (1) the data consideration provision, Section 3(c)(1)(D), constitutes a "taking" of property for a private purpose without just compensation, in violation of the Fifth Amendment and (2) the data disclosure provisions, Sections 3(c)(2)(A) and 10, are beyond Congress' Commerce Clause powers and effectuate a taking without just compensation in violation of the Fifth Amendment. Monsanto further contended that the compulsory and binding arbitration scheme provided in Section 3(c)(1)(D)(ii) violates the company's due process rights and constitutes an unconstitutional delegation of judicial power.

Following a bench trial, the district court ruled in favor of Monsanto. The court concluded that the data consideration and disclosure provisions of FIFRA are beyond Congress' Commerce Clause powers and constitute an unconstitutional taking of property in violation of the Fifth Amendment. The court held that Monsanto has a state-protected property right (based on the trade secret definition in the *Restatement of Torts* § 757 (1939)) in the data it submits to EPA, which precludes EPA from considering Monsanto's data in support of another person's registration application or from disclosing the data publicly. Section 3(c)(1)(D), the court concluded, appropriates Monsanto's "fundamental right * * * to exclude" others from use of its property, furthers private rather than public purposes, and operates as an unconstitutional taking of Monsanto's property (App. A, *infra*, 31a-32a). The Court also found that FIFRA's disclosure provisions (Sections 3(c)(2)(A) and 10) "effectively destroy" Monsanto's property, adding that disclosure is "beyond Congress' regulatory powers" because the public interest is satisfied by EPA's analysis of the pesticide's safety and by the labeling requirements

under FIFRA (App. A, *infra*, 32a-33a). The court further concluded that Congress had withdrawn the Tucker Act remedy to provide Monsanto with "just compensation," on the ground that the compensation and exclusive use provisions of Section 3 (7 U.S.C. (& Supp. V) 136a) "were intended to be the sole compensation for any taking" (App. A, *infra*, 35a). Finally, the court held that the data-compensation scheme established in Section 3 is unconstitutional because it does not provide "just compensation" and because it denies Monsanto "due process" and amounts to an unconstitutional delegation of judicial power (App. A, *infra*, 34a). The court recognized that every other court which had considered these issues had held FIFRA constitutional (see page 13, *infra*) but chose not to follow those decisions (App. A, *infra*, 36a-37a).

The district court enjoined EPA from implementing "in any manner, directly or indirectly," FIFRA Sections 3(c)(1)(D) and (2)(A), 10(b) and (d) (App. A, *infra*, 40a). In addition, it specifically enjoined "any use or consideration of or disclosure to any other person of any of Monsanto's information, research and test data, whenever submitted * * * unless [EPA] shall have first obtained Monsanto's express written permission" (*ibid.*). Both EPA and Monsanto moved to amend the judgment. EPA sought to clarify that the judgment did not preclude release of Monsanto's health and safety data to other agencies of the federal government or to Congress. EPA also moved for a stay pending appeal to this Court. Monsanto asked the court to add a new paragraph to the judgment specifying that EPA could process registrations for those manufacturers that can generate their own data or obtain the data from another manufacturer. On May 9, 1983, the district court issued an amended judgment that accommodated both EPA's

and Monsanto's requests for amendment, but denied EPA's motion for a stay (App. B, *infra*, 39a-40a). On July 1, 1983, EPA moved in this Court for a stay pending appeal. On July 27, 1983, the stay was denied. *Ruckelshaus* v. *Monsanto Co.*, No. A-1066 (Blackmun, Circuit Justice).

THE QUESTIONS PRESENTED ARE SUBSTANTIAL

The district court has declared unconstitutional several key provisions of FIFRA that effectuate Congress' express intent that the pesticide registration program be made more efficient, that competition in the industry be increased, and that the potential hazards of pesticide products be disclosed to the public. The comprehensive scheme created by Congress reflects a careful balance between the need for increased competition and the need for innovation in the pesticide industry. The scheme also accommodates private industry's interest in protecting information and the public's interest in understanding the potential risks and dangers of pesticide products. If the decision below is allowed to stand, numerous safe and effective pesticides (including new uses for pesticides) will not be registered and the public will be deprived of vital information necessary to evaluate properly a pesticide's hazards and EPA's registration decisions.

The district court decision is erroneous for several reasons. First, the court all but ignored the well-established principle that "legislative Acts adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality * * *." *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976). Second, the decision totally disregards Congress' findings concerning the need for more competition in the pesticide industry, greater efficiency in

the registration program, and public disclosure. The decision is also inconsistent with the decisions of this Court construing the Commerce Clause and the Fifth Amendment, and conflicts with the prior judicial decisions involving similar challenges to the same statutory provisions. Prior to the decision below, all courts that had ruled on the constitutionality of the data consideration and disclosure provisions had upheld them as a rational means for effectuating Congress' intent. See *Mobay Chemical Corp.* v. *Costle*, 517 F. Supp. 252 (W.D. Pa. 1981), aff'd, 682 F.2d 419 (3d Cir.), cert. denied, No. 82-241 (Nov. 8, 1982); *Pennwalt Corp.* v. *Gorsuch*, No. 80-2400 (W.D. Pa. July 23, 1982), aff'd as a companion case in *Mobay, supra; Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); *Petrolite Corp.* v. *EPA*, 519 F. Supp. 966 (D.D.C. 1981). See also *Union Carbide Agricultural Products Co.* v. *Costle*, 632 F.2d 1014 (2d Cir. 1980), cert. denied, 450 U.S. 996 (1981) (refusing to preliminarily enjoin operation of Sections 3(c)(1)(D) and 10 pending resolution of Union Carbide's constitutional challenge).[10] This Court should note probable jurisdiction to review the district court's dubious constitutional rulings, to confirm the validity of Congress' careful scheme to regulate the pesticide indus-

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[10] Subsequent to the decision in the present case, the district court in *Union Carbide* upheld the constitutionality of Section 10 and found the arbitration scheme to be an unconstitutional delegation of judicial authority. It did not otherwise rule on the data consideration provisions of Section 3 and has not yet entered a remedial order. *Union Carbide Agricultural Products Co.* v. *Ruckelshaus*, No. 76 Civ. 2913(RO) (S.D.N.Y. July 28, 1983).

try in the public interest, and to resolve the conflicting decisions of the lower courts.

1. Congress clearly has the power under the Commerce Clause to regulate the pesticide industry in a manner that promotes the public health and welfare. Congress may properly act "to prevent the flow of commerce from working harm to the people of the nation," *Mulford* v. *Smith*, 307 U.S. 38, 48 (1939), and may enact broad provisions to aid the accomplishment of these goals. See, *e.g.*, *United States* v. *Darby*, 312 U.S. 100, 121 (1941). Courts have consistently found the commerce power broad enough to permit congressional regulation of activities causing potential environmental hazards. *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 282 (1981). In addition, regulation of competition is a long-established and well-developed power of Congress under the Commerce Clause. *Bowman Transp.* v. *Ark.-Best Freight System*, 419 U.S. 281, 298 (1974); *Northern Securities Co.* v. *United States*, 193 U.S. 197, 337-338 (1904). The challenged provisions of FIFRA are a rational means for effectuating Congress' intent.

Section 10 rationally effectuates Congress' interest in minimizing the hazards of pesticide use. Disclosure enables members of the public to assess for themselves the safety and efficacy of pesticide products, many of which are inherently dangerous. Disclosure also enables members of the public to participate in and evaluate EPA's pesticide registration decisions.[11] The district court's conclusion that "the court cannot

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[11] See generally McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 Harv. L. Rev. 837 (1980).

fairly say that Section 10's public disclosure provisions are a regulation of commerce" (App. A, *infra*, 33a) is patently incorrect, particularly in light of the Constitution's "necessary and proper clause."

Section 3(c)(1)(D) also rationally effectuates Congress' desire to increase competition in the pesticide industry and to promote an efficient registration program. By removing needless barriers to market entry created by the data submission requirements of FIFRA, Section 3(c)(1)(D) promotes Congress' desire to advance competition. In addition, by reducing the burden of duplicating test data and spreading the cost of testing equitably throughout the industry, by means of the exclusive use and data compensation scheme, Section 3(c)(1)(D) enhances the efficient operation of the registration system. In holding that there is adequate competition in the pesticide industry and that the section therefore "unabashedly operates to further a private purpose" (App. A, *infra*, 32a), the district court improperly intruded upon the legislative domain. The legislative history fully supports Congress' determination that there is a need for more competition in the pesticide industry. See, *e.g.*, S. Rep. No. 95-334, *supra*, at 3, 8, 31. Accordingly, the court was not free to substitute its judgment for Congress' finding of public need. *Hodel* v. *Indiana*, 452 U.S. 314, 326 (1981). Moreover, because the Act serves a valid public purpose, the fact that private persons may also derive benefit is irrelevant. *Berman* v. *Parker*, 348 U.S. 26, 32 (1954).

2. The district court's conclusion that Sections 3(c)(1)(D) and 10 of FIFRA constitute a taking of Monsanto's property without just compensation is also erroneous. These sections deal only with health and safety data. Thus, subsequent applicants relying on Section 3(c)(1)(D) to obtain a registration must

still provide the agency with their own formulas and manufacturing processes. Section 10 prevents the disclosure of formulas and manufacturing processes in most instances. The district court correctly recognized that there is nothing in federal law that precludes the government from using the health and safety data voluntarily submitted by Monsanto to further the government's regulatory responsibilities (App. A, *infra*, 29a). The court determined, however, that Monsanto has a state-protected right based on the *Restatement of Torts* § 757 (1939) (App. A, *infra*, 29a), which precludes government use.[12]

We do not dispute that while the data remained exclusively in Monsanto's hands any trade secrets contained in the data were protected by state law. Monsanto could have preserved any trade secret in its health and safety data by forgoing the opportunity to seek a registration. It could have decided to sell or license the health and safety data to others. Monsanto, however, chose to disclose that data to EPA in exchange for commercially valuable pesticide registrations. Once Monsanto made the decision to obtain a valuable registration, the company accepted the conditions for obtaining the registration. Cf. *Almeida-Sanchez* v. *United States*, 413 U.S. 266, 271 (1973) ("The businessman in a regulated industry in effect consents to the restrictions placed upon him."). It

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[12] Significantly, under Missouri law a trade secret does not last into perpetuity. Missouri has adopted the "head start" rule which provides that a trade secret lasts for only " '[t]hat period of time which would have been required by defendants to reproduce plaintiff's products without wrongful appropriation.' " *Carboline Co.* v. *Jarboe*, 454 S.W.2d 540, 552-553 (Mo. 1970). The exclusive use period mechanism adopted in FIFRA is essentially a "head start" rule, and thus provides Monsanto with the same and perhaps even greater protection than it is entitled to under state law.

follows that Monsanto does not retain any state law right that interferes with Congress' authority to direct EPA to make internal use of data submitted to it or to disclose to the public health and safety data relevant to potential hazards posed by a pesticide. Any continuing right to confidentiality in the data submitted by Monsanto to EPA is solely a matter of federal law.[13] *Chevron Chemical Co.* v. *Costle*, *supra*, 641 F.2d at 116; *Mobay Chemical Corp.* v. *Gorsuch*, *supra*, 682 F.2d at 423.

Even if it were true that Monsanto retained a state property right in the data it voluntarily submitted to EPA, Monsanto failed to demonstrate any taking of its property by virtue of EPA's internal consideration and restricted disclosure of the health and safety data to achieve the public purposes described above. In deciding whether a particular governmental action has effected a taking, this Court focuses "both on the character of the action and on the nature and extent of the interference with rights in the [property] as a whole." *Penn Central Transp. Co.* v. *New York City*, 438 U.S. 104, 130-131 (1978). Among the factors to be considered are whether the "interference with property can be characterized as a physical invasion by government," and "the extent to which the regulation has interfered with distinct investment-backed expectations." 438 U.S. at 124. Under the principles established by this Court, a taking is "more readily * * * found when the interference with property can be characterized as a physical invasion by government * * * than when interference arises from

[13] Moreover, where, as here, Congress has specifically authorized EPA to consider and disclose health and safety data, the suggestion that the federal government's use of such data is limited by state law contravenes the Supremacy Clause. See *Hancock* v. *Train*, 426 U.S. 167, 179-180 (1976).

some public program adjusting the benefits and burdens of economic life to promote the common good." *Ibid.* In addition, a taking is more readily established where the government regulation destroys all property rights or renders the plaintiff unable to derive any economic benefit from the property. *Andrus* v. *Allard*, 444 U.S. 51, 65-67 (1979). "[T]he denial of one traditional property right does not always amount to a taking. * * * [W]here an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking, because the aggregate must be viewed in its entirety." *Id.* at 65-66. Tested by these principles, Monsanto has failed to establish a taking.

Here, of course, there is no "physical invasion" of Monsanto's property. In fact, the operation of Sections 3(c)(1)(D) and 10 do not in any way restrain or preclude Monsanto from using its data. The district court specifically found that not only does Monsanto obtain a valuable registration for its data, but it may use the data to develop new products or new uses for old products, to advertise and market its products, to obtain additional domestic and foreign registrations, to defend claims against its products, and to enhance its reputation in the scientific community (App. A, *infra*, 18a, 21a, 23a).

The district court erred in concluding that Section 3(c)(1)(D) causes a taking because it appropriates Monsanto's fundamental right "to exclude others" from its data. Interference with the right to exclude does not by itself constitute a taking. *PruneYard Shopping Center* v. *Robins*, 447 U.S. 74, 84 (1980). The "right to exclude" is merely one "strand" in Monsanto's "bundle" of rights. Since Monsanto retains significant rights in its data (App. A, *infra*,

18a, 21a, 23a), this limited interference does not constitute a taking. 447 U.S. at 84. At most, the data consideration provisions may result in competition and a concomitant reduction in profits. However, "loss of future profits—unaccompanied by any physical property restriction—provides a slender reed upon which to rest a takings claim." *Andrus* v. *Allard*, *supra*, 444 U.S. at 66. This is particularly true here, where Monsanto retains its primary sources of competitive advantage, including its product and use patents, its advertising and marketing techniques, and lead-time advantages not related to data development (App. A, *infra*, 18a-21a, 23a). Moreover, Congress did not eliminate all protection for Monsanto's data. Monsanto retains a 10-year exclusive use for data submitted on any new active ingredient registered after 1978 and is entitled to compensation for use of other data submitted after 1969 for a 15-year period. The provision of valuable replacement rights mitigates the burden of the government action and must also be taken into account in considering the impact of regulation. *Penn Central*, *supra*, 438 U.S. at 137. The present statutory scheme, designed to promote efficiency and competition while preserving innovation, is a reasonable legislative response for which the principles of "justice and fairness" embodied in the Fifth Amendment do not require compensation. See *Agins* v. *City of Tiburon*, 447 U.S. 255, 262-263 (1980); *Andrus* v. *Allard*, *supra*, 444 U.S. at 66.

Similarly, the limited interference with Monsanto's property caused by Section 10, the public disclosure provision, does not constitute a taking. As demonstrated by the district court's findings, the data at issue were "generated primarily for registration purposes" without regard to disclosure (App. A, *infra*,

21a). In fact, Monsanto has continued and accelerated its research and development efforts despite the 1978 enactment of the disclosure requirements of FIFRA (*ibid.*). It is therefore clear that disclosure does not destroy Monsanto's ability to earn a reasonable return on its investment; nor does disclosure significantly impair Monsanto's "investment-backed expectations." Furthermore, this Court has upheld similiar schemes providing for release to the public of commercially valuable information to further a legitimate public purpose. *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919); *National Fertilizer Ass'n* v. *Bradley*, 301 U.S. 178 (1937). The Court stated in *Corn Products* that a "manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." [14] 249 U.S. at 431. Finally, the 1978 Amendments did not eliminate all protection from disclosure of Monsanto's data. Formulas and manufacturing processes are protected in most in-

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[14] The district court's conclusion that the public does not need disclosure because of FIFRA's labeling requirements is unsupported. First, the court itself noted that the labels do not contain complete information (App. A, *infra*, 24a). Second, the court may not ignore Congress' determination that full disclosure of health and safety data is necessary to protect the public health and to enable full public participation in the registration process. *Hodel* v. *Indiana*, *supra*, 452 U.S. at 326. As noted above, many groups such as farm workers, chemical workers, and environmental groups request these data from EPA and retain scientists to review such data. This Court has recognized the propriety and, indeed, the desirability of obtaining public input by making information on regulatory decisions available to the public. See, *e.g.*, *FCC* v. *Schreiber*, 381 U.S. 279 (1965); *Utah Fuel Co.* v. *National Bituminous Coal Comm'n*, 306 U.S. 56, 60-62 (1939).

stances and EPA ordinarily may not disclose any data to multinational pesticide companies without the submitter's consent. Section 10(g), 7 U.S.C. (Supp. V) 136h(g). These measures attenuate even further Monsanto's taking claim.

In sum, Section 10 strikes a careful balance between industry's interest in proprietary information and the public's interest in evaluating the risks and dangers inherent in pesticide use.[15] Although Section 10 may adjust Monsanto's rights in its property, it does not destroy the property. Monsanto retains significant rights in its data. Thus, while Monsanto

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[15] A similar balance has been struck in a great number of federal statutes that authorize or require public disclosure of information submitted by private firms to the government. In particular, many federal statutes provide for disclosure of allegedly "trade secret" information concerning potential hazards to public health. For example, notwithstanding trade secrecy claims, the Toxic Substances Control Act requires public disclosure of "health and safety data" concerning chemical substances and mixtures distributed in commerce (except for manufacturing processes and some formula information), 15 U.S.C. 2613(b); the Clean Air Act requires disclosure of "emission data," 42 U.S.C. (Supp. V) 7607(a)(1); the Federal Water Pollution Control Act requires disclosure of "effluent data," 33 U.S.C. 1319(b); and the Safe Drinking Water Act requires disclosure of all data concerning drinking water contaminants, 42 U.S.C. 300j-4(d). See also 42 U.S.C. 263g (d), requiring disclosure of trade secret data concerning radiation emissions from electronic products such as microwave ovens; 42 U.S.C. 5413(c)(5), requiring disclosure of trade secret data concerning safety-related defects in mobile homes; 46 U.S.C. 1464(d), authorizing disclosure of trade secret information regarding safety defects in boats and boating equipment; and 15 U.S.C. 2217, authorizing trade secret fire protection information to be disclosed when "necessary in order to protect health and safety."

may bear some burden by virtue of this regulation, it is a burden borne to secure " 'the advantage of living and doing business in a civilized community.' " *Andrus* v. *Allard*, *supra*, 444 U.S. at 67, quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting).

3. Finally, even if operation of Section 3(c)(1)(D) or Section 10 would cause a "taking" of Monsanto's property, Monsanto is not entitled to injunctive relief. A taking will be enjoined as unconstitutional only if it has not been duly authorized, if it serves no public purpose, or if the owner will be denied just compensation for the property taken. See, *e.g.*, *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 94 n.39 (1978); *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 126-127 & n.16 (1974). Under these standards, the district court erred in concluding that Sections 3(c)(1)(D) and 10 are unconstitutional as a violation of the Fifth Amendment.

First, there can be no dispute that EPA's consideration and disclosure of Monsanto's data are duly authorized by Sections 3(c)(1)(D) and 10. Second, as demonstrated above, both sections serve important public purposes. Finally, even if the statute operated to effect a "taking," Monsanto would have an adequate remedy for seeking just compensation under the Tucker Act, 28 U.S.C. 1291. See *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732, 742-743 (D. Del. 1980), aff'd on other grounds, 641 F.2d 104 (3d Cir.), cert. denied, 452 U.S. 961 (1981); *Union Carbide*, *supra*, 632 F.2d at 1019.

The district court's conclusion that Sections 3 and 10 are unconstitutional because Congress withdrew the Tucker Act remedy in FIFRA is unsupported.

The critical question in determining the applicability of the Tucker Act is "not whether the [challenged statute] expresses an affirmative showing of congressional intent to permit recourse to a Tucker Act remedy * * *," but rather whether Congress has "*withdrawn* the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the [challenged statute] 'founded * * * upon the constitution.'" *Regional Rail Reorganization Act Cases*, *supra*, 419 U.S. at 126; emphasis in original. There is no indication in the language or legislative history of the 1978 Amendments to FIFRA that Congress intended to withdraw the Tucker Act remedy. Consequently, there is no basis for the district court's conclusion that the exclusive use and compensation provisions of Section 3(c)(1)(D) were intended to be "the sole compensation" for the operation of Sections 3 and 10.[16] The exclusive use and compensation

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[16] The district court further erred in suggesting that the Tucker Act remedy is not available because "[n]o monies were allocated by the government to insure that adequate compensation would occur" (App. A, *infra*, 36a). Such an appropriation is not customary and is in no way a prerequisite to jurisdiction of the Claims Court under the Tucker Act. As this Court stated in *Yearsley* v. *W. A. Ross Construction Co.*, 309 U.S. 18, 21 (1940), "if the authorized action * * * does constitute a taking of property for which there must be just compensation under the Fifth Amendment, the Government has impliedly promised to pay that compensation and has afforded a remedy for its recovery by a suit in the Court of Claims." Finally, the district court's view (App. A, *infra*, 36a) that the Tucker Act is not an adequate remedy because FIFRA works an "immediate taking of Monsanto's property as of the passage of the amendments to FIFRA" is unfounded. Obviously, if any taking occurs it occurs only when EPA actually considers Monsanto's data or discloses the data publicly. FIFRA itself does not automati-

provisions were meant to provide incentive for innovation and to spread the costs of producing registration data among all the beneficiaries of such data. The mere provision of exclusive use periods and a compensation scheme does not alone support the conclusion that the Tucker Act remedy has been withdrawn. In the *Regional Rail Reorganization Act Cases*, this Court rejected a similar contention. 419 U.S. at 127-128. Thus, even if Sections 3(c)(1)(D) and 10 result in a taking of Monsanto's property, the district court erred in declaring them unconstitutional and enjoining their implementation. *Regional Rail Reorganization Act Cases*, *supra*, 419 U.S. at 102.

4. In addition to finding the data consideration and disclosure provisions unconstitutional, the district court found the data compensation scheme unconstitutional on the grounds that the binding arbitration scheme does not afford Monsanto just compensation and constitutes a denial of due process in violation of the Fifth Amendment. The court also held that the scheme impermissibly "delegates judicial power to determine property rights disputes without the necessary prerequisites of Article III of the Constitution" (App. A, *infra*, 34a-35a). These issues are not ripe for judicial review and should not have been reached by the district court because Monsanto has not been a party to any arbitration under the section. *Babbitt* v.

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cally confiscate Monsanto's data. FIFRA merely provides for EPA's consideration and disclosure of the data under specified circumstances. Moreover, to the extent the district court's holding rests on concern that compensation, if required, will not precede the alleged "taking," the holding has no merit. The Fifth Amendment does not require that compensation precede the taking. *Hurley* v. *Kincaid*, 285 U.S. 95, 104 (1932).

United Farm Workers National Union, 442 U.S. 289 (1979).

Moreover, these arguments are all without merit. First, as discussed above, the intra-industry compensation scheme was not meant to provide Monsanto "just compensation" within the meaning of the Fifth Amendment, since no taking requiring compensation has occurred. Second, this Court has consistently upheld, against due process claims, the constitutionality of statutes with mandatory arbitration provisions. See *Andrews* v. *Louisville & Nashville R.R.*, 406 U.S. 320, 322 (1972); *Walker* v. *Southern Ry.*, 385 U.S. 196, 198 (1966); *Hardware Dealers Mutual Fire Insurance Co.* v. *Glidden Co.*, 284 U.S. 151 (1931). See also *Country-Wide Insurance Co.* v. *Harnett*, 426 F. Supp. 1030 (S.D. N.Y.) (three-judge court), aff'd without opinion, 431 U.S. 934 (1977). Courts regularly have upheld such arbitration requirements against claims that they provide for the determination of certain rights by nonjudicial bodies with only limited judicial review. See *Crane* v. *Hahlo*, 258 U.S. 142 (1922); *Ludwig Honold Mfg. Co.* v. *Fletcher*, 405 F.2d 1123 (3d Cir. 1969); *Edwards* v. *St. Louis-San Francisco R.R.*, 361 F.2d 946 (7th Cir. 1966). See also *Switchmen's Union* v. *National Mediation Bd.*, 320 U.S. 297, 300-301 (1943). Contrary to the district court's holding (App. A, *infra*, 34a-35a), the arbitration scheme in Section 3(c)(1)(D) does not amount to an unlawful delegation of judicial power without the prerequisites of Article III. The district court's reliance on *Northern Pipeline Construction Co.* v. *Marathon Pipe Line Co.*, No. 81-150 (June 28, 1982), is misplaced. In contrast to the 1978 Bankruptcy Act, FIFRA does not vest arbitrators with the authority to adjudicate common law

disputes or any rights other than those established solely by Section 3(c)(1)(D) itself. As the plurality opinion in *Northern Pipeline* states (slip op. 33; footnote omitted):

> [W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

Finally, even if this Court were to resolve the Article III issue in Monsanto's favor, that would not justify enjoining the entire Section 3(c)(1)(D), but only the limitation on judicial review in the fourth sentence of Section 3(c)(1)(D)(ii). See 2 C. Sands, *Sutherland Statutory Construction* § 44.04 (4th ed. 1973); Section 30, 7 U.S.C. (Supp. V) 136x (severability).

CONCLUSION

Probable jurisdiction should be noted.

Respectfully submitted.

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AUGUST 1983

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, DEFENDANT

[Filed Apr. 19, 1983]

MEMORANDUM

This matter is before the Court for a decision on the merits after a bench trial which spanned weeks and generated a 690 page transcript, numerous depositions, exhibits and affidavits. At issue is the constitutionality of Sections 3(c)(1)(D), 3(c)(2)(A) and Sections 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended in 1978, 7 U.S.C. § 136 *et seq.* Plaintiff seeks an injunction and declaratory judgment blocking operation of the Sections in question. Both parties have ably presented and briefed their respective positions and have provided the Court with a concise and thorough foundation for its decision.

Pursuant to Rule 52 of the Federal Rules of Civil Procedure, the Court hereby makes the following findings of fact and conclusions of law. Any finding of fact equally applicable as a conclusion of law is

hereby adopted as such and, conversely, any conclusion of law applicable as a finding of fact is adopted as such.

Findings of Fact

1. Plaintiff, Monsanto Company, is incorporated in the State of Delaware and has its principal place of business in St. Louis County, Missouri. Plaintiff owns and operates its principal corporate and administrative offices, and its major research facilities in St. Louis County, Missouri. It is licensed to do business in the State of Missouri and resides in this judicial district.

2. Defendant is the Acting Administrator of the United States Environmental Protection Agency (hereinafter EPA), and is charged with the implementation, administration and enforcement of the Federal Insecticide, Fungicide and Rodenticide Act. Defendant is sometimes hereinafter referred to as the "Administrator".

3. Since FIFRA was first enacted in 1947, it has required the registration of all pesticides shipped in interstate commerce. In order to obtain the registration of a pesticide under FIFRA an applicant was required to support its application for registration with extensive research and test data demonstrating that the product would comply with FIFRA, that is, that the pesticide was effective for its recommended uses, and that it would perform its intended functions without unreasonable adverse effects on man, vertebrate animals and desirable vegetation. If use of the pesticide for which registration was sought could result in residues in or on raw agricultural commodities, the applicant was also required to submit in support of its application for registration extensive research and test data relating to the pro-

posed application of the pesticide, its toxicity, the manner in which it was metabolized, its degradation, and its residues. This information was also required to be submitted in a petition for a tolerance for the pesticide for which registration was sought.

Until 1970, the Secretary of the United States Department of Agriculture (hereinafter USDA) administered FIFRA. Also, until 1970, the Secretary of Health, Education and Welfare, by and through the Food and Drug Administration (hereinafter FDA), was authorized to establish tolerances for pesticide chemicals in or on raw agricultural commodities under Section 408 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 346(a). These administrative functions of the USDA and FDA were transferred to EPA in December, 1970, by Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623 (1970).

4. The term "pesticide" is defined in Section 2(u) of FIFRA to mean (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or dessicant." (FIFRA Section 2(u)).

The person holding the registration that permits the product to be sold or distributed is known as a "registrant."

5. One of the two basic kinds of pesticide products is an "end-use product" or "formulated product" designed to be used as sold or after dilution by the user against pests. An end use product contains at least one active ingredient which is defined in Section 2(a) of FIFRA as "an ingredient which will prevent, destroy, repel or mitigate any pest" or which will defoliate, dessicate or regulate the growth of

plants. In order for an end use product to be used against pests and plants the active ingredient normally must be combined with "inert ingredients" which dissolve, dilute or stabilize the active ingredient or otherwise improve its pesticidal performance.

6. A second basic kind of pesticide product is a "manufacturing-use product" which is a product designed to be used to manufacture an end use product. A manufacturing use product generally is a relatively pure form of the active ingredient and is sometimes referred to as a technical product.

7. Approximately 40,000 pesticide products are currently registered under FIFRA. Most of these registered products are end use products (about 2,500 are registered for manufacturing use). Many of these end use products are very similar, containing the same active ingredient and closely similar inert ingredients.

8. A relatively few firms actually produce all the active ingredients. Of the more than 4,000 registrants, therefore, most are engaged in producing end-use products, using active ingredients they purchase (these firms are usually referred to as "formulators"). Some firms, such as Monsanto, produce both active ingredients and end-use products. A firm which produces an active ingredient may use it solely for incorporation into its own end-use products, may sell it (in the form of a manufacturing-use product) to formulators, or may do both.

9. Most of the research and testing on pesticides, and invention and development of new active ingredients, has been done by a few, relatively large companies of which Monsanto is one. Most, if not all, firms of this type, including Monsanto, are engaged in foreign or multinational pesticide sales.

10. Monsanto is involved in research and development activities to attempt to develop new pesticide products. These research and development efforts have resulted in the expediture of millions of dollars by Monsanto and their efforts have resulted by the granting of patents for many of the new active ingredients which Monsanto has developed.

11. A company's decision to develop pesticides requires it to make major commitments long before it can anticipate developing a commercial pesticide and even longer before it can expect any return on its investment. First, the company must synthesize, test and evaluate candidate pesticides typically for 4 to 8 years before it will identify a commercial candidate. It must then conduct extensive research for at least 6 additional years, including 2 years to obtain registration, before it can anticipate first marketing a product. Generally, a further 4 to 8 years will elapse before that product reaches a point where its costs of discovery, development and commercialization have been recovered. Second, the company must commit to the employment of a large scientific research group representing many disciplines, and to the acquisition of the necessary physical facilities and sophisticated equipment to conduct the intensive research required to assure some reasonable probability of success in discovering and commercializing a candidate pesticide. Third, any such company must usually commit to the expenditure of $5 million to $15 million annually for several years before it will develop a potential commercial pesticide candidate. Even then, it will not know whether the candidate will become a commercial product until it has conducted further evaluation for an additional four or more years. This further evaluation could dictate

that the candidate be rejected at any point during its development, even in the final year of its further evaluation. A key element in the above analysis is whether the chemical can be patented, thereby assuring Monsanto monopoly protection for the patented chemical, use or process during the period of the patent.

12. Once a target is selected, a company must devise extremely efficient, unique and technically sound ways of determining what compounds should be synthesized. The Company's chemists are not only concerned with synthesizing new chemicals, but equally important, are concerned with new chemical processes, techniques, and methods of synthesis to facilitate their invention of such new chemicals with commercial potential. Once a company decides that a new area of chemistry might be fruitful, these chemists then proceed to develop and synthesize new compounds in that area of chemistry. These new compounds are referred to biologists who determine whether they are biologically active and whether they are pesticide candidates. This biological information is crucial in making the difficult technical judgment whether a compound is worthy of further study. The biologists and the chemists then examine and discuss the results to determine which directions, if any, offer further leads. Using the knowledge obtained from these discussions, the chemists synthesize more new compounds in the directions in which leads are expected. This constant dialogue takes place between literally dozens of organic chemists and biologists and is what ultimately produces the lead which results in a new commercial pesticide.

Decisions on most of the thousands of chemicals synthesized by plaintiff are made after an initial eval-

uation called a primary screen which allows plaintiff to determine the probability of a compound becoming commercially successful. With most compounds, this probability is virtually zero, and these compounds are rejected. However, Monsanto can and usually does seek patents on any chemicals with commercial potential, even if they do not themselves decide to develop those chemicals.

13. When EPA registers a pesticide product under FIFRA, what it actually is doing is approving the composition and labeling for that product and allowing that product to then be sold with the approved labeling being use.

14. A label must contain: 1) general information such as the name of the company, the type of product, and the registration number; 2) hazard statements; 3) directions for use; and 4) limitations on use.

15. The hazard statements required to appear on the label include precautionary statements and a statement of physical hazards. The precautionary statements, *inter alia*, inform the user of the relative toxicity of the pesticide and set out an antidote in the event a person is poisoned by the pesticide. The statement of physical hazards contains information regarding things such as the flammability of the product, how the product should be stored, and how the container should be disposed.

16. The directions for use set forth the manner in which the pesticide is to be used. It is illegal for any person to use a pesticide for any purpose other than that stated in the directions for use. With respect to agricultural chemicals the directions for use inform the user of the type of crops to which the pesticide may be applied, the pests which it can be used to control, the dosage rate which must be used, and the method of application.

17. The limitations on use include restrictions such as a pre-harvest interval which provides that the pesticide must be applied more than a certain number of days before it is harvested or a rotational crop limitation which provides that specifically-named crops should not be planted for a certain time in the field to which the pesticide has been applied.

18. FIFRA was originally enacted in 1947 (P.L. 80-140), 61 Stat. 163). Under the terms of the original statute pesticide manufacturers were required to obtain a registration from the United States Department of Agriculture (USDA) before distributing or selling their pesticide products in interstate commerce. 7 U.S.C. § 135(a) (1970).

19. In order to obtain a pesticide registration under 1947 FIFRA the applicant for registration was required to file with USDA a statement which included the following information:

> (1) the name and address of the applicant for registration and the name and address of the person whose name will appear on the label, if other than the applicant for registration;
>
> (2) the name of the economic poison;
>
> (3) a complete copy of the labeling accompanying the economic poison and a statement of all claims to be made for it, including the directions for use; and
>
> (4) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based.

7 U.S.C. § 135(a) (1970).

The test data required under 7 U.S.C. § 135b(a)(4) essentially consisted of efficacy data and limited tests concerning the health and safety dangers of the pesticide products, (particularly its acute toxicity).

20. On October 20, 1972, FIFRA was amended by the Federal Environment Pesticide Control Act of 1972, (Pub. L. No. 92-516, 92d Cong., 2d Sess., October 21, 1972), (FEPCA). Pursuant to this amendment, the registration requirements were extended to pesticides shipped in intrastate commerce and authority was provided for the classification of pesticides and the regulation of their use. All of the requirements for the submission of research and test data were retained. Moreover, the data to be submitted under the 1972 amendments was the same general kinds of information that were required under the 1947 Act. The requirements for obtaining a registration were also strengthened so that the 1972 amendments were described as having "changed FIFRA from a labeling law into a comprehensive regulatory statute that . . . more carefully control[s] the manufacture, distribution and use of pesticides." H.R. Rep. No. 92-511, 92 Cong., 1st Sess. 4 (1971).

21. Section 3(c)(1)(D) of FIFRA sets forth the requirements for submission by an applicant for registration of information, research and test data to support his application. This Section as enacted in 1972 provided as follows:

> (D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 10(b). If the

parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstanecs. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If the owner of the test data does not agree with said determination, he may, within thirty days, take an appeal to the federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. In no event shall the amount of payment determined by the court be less than that determined by the Administrator.

22. In Section 3(c)(1)(D) as enacted in 1972, Congress authorized the Administrator to use and consider information, research and test data submitted by a previous applicant for registration to support the application of a subsequent application, but only upon satisfaction of two preconditions. Although the Administrator could use any and all data previously submitted under FIFRA for purposes of determining the adequacy of the particular data submitted by an applicant to obtain a specific registration, the Administrator could not use any of the previously submitted data for the benefit of such applicant, that is, in support of his application, *unless the owner of the previously submitted data first granted his permission or the applicant for whose benefit the previously submitted data would be used offered to pay reasonable compensation to its owner. If, however, any of the previously submitted data to be considered in support of the application contained or related to trade secrets or other information protected from dis-*

closure by Section 10(b) of FIRFA, including confidential commercial information, then without the owner's permission it could not be used at all.

23. Section 10 of FIFRA relates to the information, research and test data of an applicant which contains or relates to trade secrets or other confidential or privileged commercial or financial information. This data was prohibited from disclosure under Section 10 as enacted in 1972 which then provided in part as follows:

> (b) *Disclosure.* Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to *trade secrets or commercial or financial information obtained* from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator. (emphasis added).

24. In an attempt to resolve controversy which had developed about the effective date of Section 3(c)(1)(D) and the data to which that section applied, Congress enacted FIFRA of 1975, Pub. L. No. 94-140, 89 Stat. 725 (1975 amendments). The 1975 amendments revised Section 3(c)(1)(D) to read in pertinent part as follows:

> Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, *except that data submitted on or after January 1, 1970,* in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other applcation for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by Section 10(b). *This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972.* (Emphasis added).

25. The 1978 amendments completely rewrote Section 3(c)(1)(D) to remove the "trade secret" prohibition established by the 1972 amendments. The result of this rewriting is now embodied in Section 3(c)(1)(D). That scheme no longer prohibits the consideration of data based on its status as a trade secret but rather creates a system whereby the "age" of the data, and the "newness" of the active ingredient to which the data relates, determine the amount of protection which will be afforded. By its terms the 1978 Act established three categories of test data available for consideration by EPA under varying conditions. With respect to data submitted to support a registration application initially granted after September 30, 1978 (post-1978 data), the Administrator may not consider such data to support an application of another person (applicant), without the permission of the original data submitter, for a period of

ten years following the initial registration. Therefore, data submitters are entitled to a ten-year period of "exclusive use" for post-1978 data. 7 U.S.C. § 136(a)(c)(1)(D)(i). With respect to data submitted after December 31, 1969 (post-1969 data), the Administrator may consider such data to support an application by another person, without the permission of the original data submitter, for a period of fifteen years following submission of the data only if the subsequent applicant has offered to compensate the original data submitter. Disputes as to compensation are submitted to binding arbitration, unreviewable by any court absent fraud or misrepresentation. An original data submitter who refuses to participate in the arbitration proceeding forfeits the right to compensation. Thus, data submitters are entitled to a fifteen-year period of compensation for use of post-1969 data. Data submitted after 1978, for which ten years of exclusive use is assured, also receives five years of compensation upon expiration of the exclusive use period. Finally, data submitted before 1970 may be considered by the Administrator to support the application of another application without the permission of the original data submitter and without an offer of compensation having been made. *Chevron Chemical Co.* v. *Costle*, 499 F. Supp. 732, 735-36, 740 (D. Del. 1980), *aff'd* 641 F.2d 104 (3rd Cir.), *cert. denied*, 452 U.S. 961 (1981).

26. The amendments to Section 3(c)(1)(D) were enacted because Congress believed that the "trade secret" prohibition created by the 1972 amendments was a deterrent to desirable competition in the manufacture and sale of pesticide products in commerce and in practice acted as a *de facto* extension of the period of patent protection beyond the 17-year period established by statute. S.Rep. No. 95, 334 at 3, 8, 31.

27. The "exclusive use" and compensation provisions in Section 3(c)(1)(D) were viewed as an appropriate reward for innovation while providing, at the same time, a fair and less expensive procedure for producing pesticide safety data. 124 Cong. Rec. § 15, 303-04 (Sept. 18 daily ed.)

28. Section 3(c)(2) of FIFRA was redesignated Section 3(c)(2)(A) by the 1978 amendments. Prior to the 1978 amendments, Section 3(c)(2) was limited by Section 10 which, in Section 10(b), absolutely prohibited the public disclosure of information containing or relating to trade secrets or confidential commercial information. Section 3(c)(2)(A) continues to be limited by Section 10, but Section 10 as amended in 1978 provides that in Section 10(b) that:

> *Disclosure*: Notwithstanding any other provision of this Act, and subject to the limitations in subsections (d) and (e) of this section the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, *information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator* (emphasis added).

The 1978 amendments also added a new Section 10(d) which provides in pertinent part as follows:

> *Limitations*: (1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or

with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. Provided, that the use of such data for any registration purpose shall be governed by Section 3 of this Act. Provided further, that this paragraph does not authorize the disclosure of any information that—

(A) *discloses manufacturing or quality control processes,*

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. (emphasis added)

29. The 1978 amendments added a new Section 10(g) prohibiting disclosure to foreign and multinational companies which provides in pertinent part as follows:

Disclosure to Foreign and Multinational Pesticide Producers. (1) The Administrator shall not

knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

(3) Section 1001 of Title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.

30. Section 10(f) is another new section that was added by the 1978 amendments. That section establishes a criminal penalty more stringent than that provided by the Trade Secrets Act, 18 U.S.C. § 1908, for wrongful disclosure of confidential or trade secret data by a government employer or contractor. (FIFRA Section 10(f), 7 U.S.C. § 136h(f).

31. The changes in 10(b), (d) were designed to further the public's right to know the basis for agency registration decisions. 123 Cong. Rec. § 13,091 (July 29, 1977 daily ed.). Also notable is the fact that a data submitter's manufacturing or quality control processes is not to be disclosed.

32. In order to support the registration of its products under FIFRA, as amended in 1978, plaintiff submits to defendant, information, research and test data of the following types: (1) efficacy studies; (2) phototoxicity studies; (3) metabolism and residue studies; (4) environmental chemistry studies; (5) toxicology studies; (6) fish and wildlife studies; and (7) manufacturing studies and information. This the data that Section 3(c)(2) as limited by Section 10, discloses. The research expended by Monsanto to provide the above data to register its products is not only time staking but involves the expertise of highly trained scientists. Monsanto utilizes sophisticated methods to adduce the necessary data, and the evidence indicated, that Monsanto is one of the leaders in the field, especially with respect to Monsanto's use of radiolabeling. Monsanto maintains that the direct historical cost incurred to develop the information, research and test data submitted by it

under FIFRA to secure, maintain and expand the registration of its products is in excess of $23,600,000.00. The Court finds that figure a fair approximation of Monsanto's costs in this area.

33. Much of the information, research and test data submitted by plaintiff to the EPA under FIFRA is and has been confidentially maintained by plaintiff with stringent security measures taken to preserve its secrecy.

34. The information, research and test data developed by and submitted by plaintiff under FIFRA is used by plaintiff to develop additional formulations and to expand uses of its registered products.

35. Development of plaintiff's information, research and test data by a competitor would be extremely difficult, if at all possible, and in any event would require the exercise of highly sophisticated scientific expertise and ingenuity for thousands of man-years as well as the expenditure of enormous sums of money.

36. Disclosure of plaintiff's information, research and test data certainly enhances a competitor's ability to conduct research on identical or similar competing products and might result in the development of new products.

37. A number of other companies are, as is plaintiff, engaged in the discovery and development of pesticide products in the United States and worldwide, and these companies compete with plaintiff.

38. Pursuant to 35 U.S.C. § 134, the issuance of a patent grants the patentee the exclusive right to make, use and sell the patented invention (in this case the pesticide chemical, use or formulation) for a 17 year period.

As previously indicated, patents on newly discovered pesticide compounds are normally applied for

early in the development process and before the substantial amounts of information, research and test data submitted to support a registration are generated. The patent, if issued, does not provide protection for the research and test data submitted in support of an application for registration.

39. Upon expiration of the 17-year period of patent protection, the patent law no longer prohibits companies from making, using, or selling the formerly patented product. In the case of formerly patented pesticide chemicals, the expiration of the patent period by itself is not sufficient to allow companies to legally sell pesticide products containing that active ingredient, because FIFRA requires those companies must first obtain a pesticide registration before selling their pesticide products. Under the 1972 and 1975 amendments, a data submitter could prevent a subsequent application from relying on data it had submitted to EPA and thereby prevent that applicant from obtaining a registration unless the applicant submitted his own information.

40. Monsanto frequently enjoys most of the full term of patent protection after it has initially registered a pesticide chemical. Further, new uses, manufacturing processes, formulations, or other elements important to the commercial success of the product may also be eligible for patent protection.

41. During the period of patent monopoly protection, Monsanto and other pesticide companies are also able to establish other significant competitive advantages which last beyond the period of patent protection. During the period of patent protection Monsanto is able to establish "name recognition" for its trademarks through advertising as well as the "goodwill" which it receives as the only supplier of an effective product.

42. In making its decision to proceed with the development of a pesticide, Monsanto must consider a variety of factors. Included among the factors which Monsanto must consider are the availability of patent protection, the availability of raw materials, the environmental control requirements which will be imposed on the manufacture of the chemical, and the potential market for the chemical. Successful development in light of these factors can greatly enhance Monsanto's competitive advantage.

43. During the period of development of data to support an application for pesticide registration of an active ingredient, Monsanto must also secure a reliable source of raw material supplies, develop manufacturing technology and build large-scale production facilities, secure necessary environmental and other permits, develop formulations for the marketed product, and establish markets. All of these steps together require a period of several years and represent a "lead time" advantage which Monsanto enjoys over any competitor.

44. Before a "me-too" applicant can secure a registration which involves Agency consideration of Monsanto data, that applicant must supply its own formula and manufacturing process information and all the data necessary to establish that its product is actually like the Monsanto product in every relevant respect from the standpoint of applicability of the data submitted by Monsanto.

45. Monsanto is engaged in the business of manufacturing and selling synthetic fibers and chemicals. Monsanto is divided into five operating companies (units). One such unit, Monsanto Agricultural Products Company manufactures and sells pesticides. In 1980 it accounted for approximately sixteen per cent (16%) of its operating income. That substantial

percentage of plaintiff's operating income is primarily due to the sales and profits of plaintiff's herbicides. The costs of research and development within the Agricultural Products Company are ordinary business expenses for tax purposes.

46. Despite the passage of the 1978 amendments to FIFRA, Monsanto continues to expand research and development and to submit extensive data to EPA.

47. Although Monsanto has refused to acknowledge the economic value to it conferred by the compensation provisions of § 3(c)(1)(D), it has received offers to pay from potential "me-too" registrants. EPA data guidelines provide the means for companies like Monsanto and "me-too" registrants to identify what kinds of studies are compensable. However, there are no discernible guidelines outlining the factors which constitute just compensation for use of Monsanto's data.

48. The data which Monsanto submits in support of its applications, although generated primarily for registration purposes, also serves other purposes including to provide information necessary to protect the workers who manufacture the chemical and the researchers who test it, to use for defensive purposes in product liability lawsuits, to spur further research and development, and to obtain registrations in foreign countries.

49. Most of Monsanto's competitors in the research and development field are large foreign or multinational companies like itself. Thus, Section 10(g) of FIFRA does not directly *authorize* disclosure to Monsanto's foreign or multinational competitors of health and safety data otherwise disclosable to the public pursuant to Section 10(d). Still, the Court registers considerable doubt as to the effectiveness of FIFRA's disclosure provisions. Indeed, EPA all but

admitted that there were certain situations in which the agency could not block the disclosure of information to multinational corporations (e.g., those multinational corporations that take over a national corporation) or foreign governments presumably even those governments unfriendly to the interests of the United States.

50. Much of plaintiff's information, research and test data that it has submitted under FIFRA to EPA and its predecessor agencies contains or relates to trade secrets as defined by the Restatement of Torts and Confidential, commercial information.

51. Plaintiff has certain property rights in its information research and test data.

52. Information, research and test data submitted under FIFRA can be evaluated by the EPA without the necessity of public disclosure.

53. Groups such as environmental organizations interested in protecting man and the environment from the effects of these dangerous pesticide chemicals, farmworkers' unions which serve to protect the interest of farmworkers who are directly exposed to the pesticides used in the fields where they work, and union groups which represent the workers in the chemical industry who manufacture pesticides, are interested in reviewing pesticide health and safety data. Indeed, many of the disclosure requests that EPA receives pursuant to Section 10 of FIFRA come from these types of groups.

54. Except for amounts of data within the manufacturing area, for example, the confidential statement of formula and the manufacturing process, the good portion of plaintiff's information, research and test data falls within that which would be disclosed to the public under Section 10 of FIFRA.

55. Defendant now has pending before her applications for registration submitted by plaintiff's competitors which will require defendant to use plaintiff's information, research and test data in order to grant them. Unless the relief sought by plaintiff is granted, defendant will use plaintiff's information, research and test data, including information, research and test data which is or contains trade secrets to grant these registrations as provided by Section 3(c)(1)(D) of FIFRA and, thereafter, will disclose such information, research and test data to members of the public as provided by FIFRA Section 10.

56. Monsanto would suffer a competitive advantage should its competitors obtain Monsanto's health and research product. The use or consideration for or disclosure to any third party by defendant of plaintiff's data will irreparably injure plaintiff in the conduct of its business and will confer an immediate and substantial competitive advantage upon its competitors, including foreign government-owned pesticide producers by eliminating the significant lead-time advantages enjoyed by plaintiff, by advancing significantly the state of such competitors' technology and by permitting the registration of their products, both in the United States and foreign countries, without their incurring the enormous expenditure of time and money for research and development which plaintiff has incurred.

57. Nothing in FIFRA Section 3 or Section 10 limits Monsanto's continued use of its research results to develop new products or new uses for old products, to advertise and market its products, to defend against legal or advertising claims adverse to the product, or to enhance Monsanto's reputation in the scientific community.

58. EPA has adopted internal and published interim procedures to implement the disclosure provisions of § 10. The procedures provide a mechanism to identify persons to whom disclosure is prohibited by § 10(g). They also permit full access by data submitters to the district court review provisions of § 10 prior to release of any information claimed confidential by the submitting company.

59. Through the addition of Section 10(d), Congress has now made available for disclosure efficacy data, metabolism and residue data, environmental chemistry data, toxicology data and fish and wildlife data, regardless of whether that data qualifies as "trade secret" under the Restatement of Torts standards. In Section 10(d)(1)(A), (B) and (C), however, Congress has prohibited EPA from routinely disclosing "any information that (A) discloses manufacturing or quality control processes. . . ."

60. The da[illegible] that is available to be disclosed under Section 10(d)(1) has health and safety significance.

61. Labeling provides instructions for handling and general indications of the acute toxicity of the product, but does not elaborate the scientific basis for this information.

62. Scientific training is required to understand much of the Section 10 data because of its technical nature.

63. The EPA has the ability to obtain independent scientific review and evaluation of the information, research and test data submitted to it under FIFRA in a manner which does not compromise its confidentiality and the competitive advantage to the company which said information, research and test data provides without the necessity of public disclosure by utilizing such groups as the Scientific Advisory Panel

of EPA which consists of outside scientists who are experts in certain fields including toxicology, medicine, metabolism and physiology. The Scientific Advisory Panel reviews information, research and test data presented to it by both EPA and companies and makes recommendations to EPA for actions to be taken, which EPA may or may not choose to follow.

64. In cases where an applicant was seeking a registration for a product or use not previously registered under FIFRA, USDA generally required that applicant to supply efficacy data and limited health and safety data to demonstrate that the product for which registration was sought was safe and effective when used as directed. However, the majority of the applications received by USDA, were for pesticide products and uses which were the same or substantially the same as products that had previously been registered. This type of application is commonly referred to as a "me-too" application.

65. The Pesticide Regulation Division of the USDA was divided into several branches, one of which was the Registration Branch. The Registration Branch was responsible for the review of applications for pesticide registrations. The registration branch was divided into several sections which divided the review function by types of pesticide.

66. Plaintiff's witness, Dr. Harry Hays, was director of the Pesticide Regulation Division from 1966-1969. Mr. Gregory A. Rohwer, also plaintiff's witness, was detailed to the Pesticide Regulation Division as Acting Director of that division between 1969 and 1970. Mr. Harold G. Alford was an Assistant Director of the Pesticide Regulation Division in charge of the registration branch between 1960-1970 when the pesticide registration responsibilities were

transferred from USDA to EPA. At various times between 1967-1970, defendant's witness, Mr. Ray Landolt, worked in the registration branch and actually participated in the process of reviewing applications.

67. In order to carry out the established use patterns system of registration, the USDA established by regulation a list of active ingredients for which there was adequate toxicology data available to support a registration. This list, known as "Interpretation 18" was first published in 1949 and was updated in 1954 and 1962. Each entry identified the active ingredient and contained information concerning the registered uses of the pesticide and its formulations as well as a sample of appropriate hazard labeling for products containing that active ingredient. This list apparently included both patented and unpatented products, including Monsanto products and the majority of data in support of these pesticide registrations was already in the public domain.

68. During the period that the USDA administered FIFRA, it was its policy that the data developed and submitted by companies such as plaintiff be maintained confidentially by the USDA and was not to be disclosed without the permission of the data submitter.

69. During the period the USDA administered FIFRA, it was also its *policy* that the data developed and submitted by companies such as plaintiff could not be used to support the registration of another's product without the permission of the data submitter.

70. Two former Directors of the Pesticide Regulation Division know of no instance in which any such use without permission was made. Further, if any such use without permission was made, it was con-

trary to the policy of the Pesticides Regulation Division. No person in the Division other than the Director had the authority to adopt or change the policy of the Division.

71. Data in the published literature or which had been developed by governmental agencies could be used by all without restriction, and for older products such as DDT this data was often sufficient to support registration without requiring the submission of data by an applicant.

72. These older products referred to in Finding of Fact No. 71 were known as "commodity" products. Examples of such products included 2,4-D and 2,4,5-T.

73. Plaintiff and other companies were granted pesticide registrations for certain of these commodity products without the submission of data in support of said registration because publicly available data supported said registrations. This was consistent with the USDA policy as set forth in Finding No. 69.

74. Prior to October 21, 1972, with the exception of two registrations granted to Aceto Chemical Co., Inc., on July 17, 1972 and July 24, 1972, no competitor of plaintiff was granted a pesticide registration on other than a commodity product, based on data submitted by plaintiff.

75. Plaintiff had no knowledge of either of the pesticide registrations referred to in Finding No. 74, prior to their being granted.

76. Plaintiff was not advised of either of the applications for registration referred to in Finding No. 74, prior to their being granted.

77. The evidence in the record did not establish that at any time plaintiff had any knowledge that the policy of USDA referred to in Finding No. 69 regarding treatment of information, research and test

data developed and submitted by a pesticide producer was ever violated. Further, the evidence establishes that two former Directors of the Pesticide Regulation Division were unaware of any violation of said policy.

78. The evidence establishes that if any policy other than that referred to in Finding No. 69, regarding information, research and test data developed and submitted by a pesticide producer was ever in effect at any time, such policy was never written and made available to the public or Monsanto.

Conclusions of Law

The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331(a), 7 U.S.C. § 136n(a).

In order for Monsanto to succeed in this lawsuit, it must establish the following: (1) that Monsanto has an entitlement created by federal or state law in the data it submits; (2) that EPA's use and public disclosure of said data constitutes a "taking" within the meaning of the Fifth Amendment; (3) that the compensation provisions provided by FIFRA are inadequate and that a Tucker Act remedy is not available. Monsanto must prevail on each of these issues in order for declaratory and injunctive relief to be proper. The Court will employ the above analysis to each of the challenged provisions (§ 3—Use Authority), (§ 10—Disclosure Authority).

Plaintiff maintains that two grounds exist for finding its data is constitutionally protected property. First, Monsanto points to federal law where it is contended that regulations and statutes prohibited the disclosure of a registrant's research and data. Second, Monsanto looks to Missouri's protection of trade secrets as defined in § 757 of the Restatement of Torts (1939).

The evidence in this lawsuit showed that under the 1947 version of FIFRA, no regulations or statutory source authorized the disclosure of data submitted in support of an applicant's labeling claims.[1] Moreover, the Trade Secrets Act, 18 U.S.C. § 1905, provided criminal penalties for unauthorized disclosure of trade secrets by federal officers or employees. At most, the above evidence establishes only a right of non-disclosure by the EPA. None of the federal provisions relied upon by Monsanto purport to create a federal entitlement in law to the data submitted pursuant to FIFRA. The Court finds that there was no federal property right in Monsanto's research.

The crux of Monsanto's property argument is that, as interpreted by the Eighth Circuit, Missouri has recognized a property right in defendant's data through its recognition of intellectual property expressed in the Restatement definition of trade secrets.[2] *Sandlin* v. *Johnson*, 141 F.2d 660 (8th Cir.

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[1] Nevertheless, it was not until the 1972 Amendments to FIFRA that provisions in FIFRA itself restricted the EPA's ability to consider one company's data in support of another company's application. See FF 22.

[2] § 757 provides:

> One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if
>
> (a) he discovered the secret by improper means, or
>
> (b) his disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or
>
> (c) he learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or
>
> (d) he learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.

1944). Monsanto's trade secrets in the data it submitted is a separate and distinct specie of intellectual property than afforded protection by the patent laws. *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470 (1974). It is well settled that property rights are "created and their dimensions are refined by existing rules or understandings that stem from an independent source such as state law." *Board of Regents* v. *Roth*, 408 U.S. 564, 577 (1972).

Defendant does not controvert the fact that Monsanto enjoys certain property rights in its information, research and test data, however, it is defendant's position that none of these rights affect the federal government's consideration and disclosure of the data. The Court cannot agree with the EPA's characterization. The Restatement specifically prohibits disclosure of trade secrets without privilege. Internal use of Monsanto's data was never a stated risk inherent in submitting the data to EPA. While internal use by EPA does not literally involve disclosure of confidential data, it implicitly amounts, for all practical purposes, to disclosure of the data to Monsanto's competitors and the concomitant use of that data by Monsanto's competitors. The Court believes the Restatement's protection of trade secrets is intended to reach such constructive disclosure and use situations. *See generally U.S.* v. *General Motors Corp.*, 323 U.S. 373 (1945) (Constitution protects every sort of interest the citizen may possess in his property). Therefore, the Court finds that Monsanto possessed a cognizable property right in the data submitted to EPA under § 3 pursuant to FIFRA.[3] The property rights

[3] It follows that if Monsanto had a property interest in preventing the internal use of its data by the EPA, then a property interest certainly attached in the non-disclosure of said data by the EPA. Both the Restatement, Trade Secrets Act, and prior agency prac-

Monsanto possesses in its intellectual property (data) are the rights to exclude others from the enjoyment of such data in particular, the right to prevent the unauthorized use and the right to prohibit disclosure of its data.

The next question is whether the EPA's consideration and disclosure of Monsanto's pre-1969 and post-1970 data causes an unconstitutional taking of plaintiff's property.

No set formula for determining what constitutes a taking has been articulated by the Supreme Court, however, the Court has stressed certain significant factors in what is essentially a factual inquiry: (1) nature of the invasion by the government; (2) economic impact on the owner's use of the property, particularly to the extent the regulation interferes with the distinct "investment backed" expectations; (3) public program or interest designed to benefit from the regulation. *Penn Central Transportation Co.* v. *New York*, 438 U.S. 104, 124-28 (1978); *see U.S.* v. *Darby*, 312 U.S. 100 (1941).

Section 3(c)(1)(D), which deals with agency use of Monsanto's data, does implicitly disclose plaintiff's data to its competitors. These competitors have not "contributed in money, services negotiations, skill, foresight or otherwise" to its creation. *Thompson* v. *Consolidated Gas Utilities Corp.*, 300 U.S. 55, 78 (1937). In effect, the 1978 amendments to FIFRA give Monsanto's competitors a free ride at Monsanto's expense. The fundamental right of Monsanto and its property—the right to exclude—is appropriated by § 3(c)(1)(D). *See Kaiser Aetna* v. *U.S.*, 444 U.S.

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tice demonstrate that Monsanto could reasonably expect that its data would be kept confidential and would not enter the public domain.

164, 179-80 (1979). Moreover, the economic impact of § 3(c)(1)(D) is substantial and impairs Monsanto's "investment backed" expectations.

The Court also finds that § 3(c)(1)(D) unabashedly operates to further a private purpose. Internal use of Monsanto's data can only enrich its competitors. The public stands little to gain from § 3(c)(1)(D). This is not a situation where competition is sparse or non-existent, to the contrary, the trial record amply demonstrates the competition and the pesticide industry as healthy and vibrant.

The Court is aware of the deference which must be shown Congressional pronouncements of what constitutes a public purpose. *Berman* v. *Parker*, 348 U.S. 26, 32 (1954). Nevertheless, the Court would be abdictating its responsibility to follow the Constitution if it did not rationally analyze laws which, in the name of public policy, mandate the forced sharing of property and markets created by one person for the benefit of private parties. *Thompson*, 300 U.S. at 78-79; *U.S.* v. *Carolene Products*, 304 U.S. 144, 147 (1938).

Section 3(c)(1)(D)'s interference with Monsanto's property is significant in comparison to the purported public good to be served. The EPA's internal use of Monsanto's property to support the registrations of Monsanto's competitors is not merely a change in the general law, but a destruction and therefore a taking of Monsanto's property.

Section 10 authorizes the public disclosure of test data and such matters as the effects of pesticides on human, plant and animal life. This information is initially scrutinized by the EPA (which has available to it all the scientific resources of the federal government and also of many private foundations and con-

sultants it may choose) to determine whether the submitted product is safe and effective. The presence of a registered product on the market is in itself evidence that the EPA has satisfied itself that the statutory objectives of FIFRA have been met. Furthermore, the product's label provides fair information as to what is being sold and fairly sets forth the nature, contents and purpose of the product.[4] Therefore, the product's label provides the public with the assurance that the product is safe and effective and with the knowledge of the product's qualities. All that is accomplished by publicly disclosing the various data (property) submitted by Monsanto is to permit the public to share in the regulation of the pesticide industry. The cost of this "sharing" is that Monsanto's data is permanently committed to the public domain and thus effectively destroyed.

The Court cannot fairly say that Section 10's public disclosure provisions are a regulation of commerce. The public interest in seeing that safe and effective products are marketed is satisfied by the EPA's painstaking analysis of the complicated data submitted by Monsanto to register its products. The product's label effectively conveys the information the public needs to make an informed decision. Public disclosure of Monsanto's data by operation of § 10 is beyond Congress' regulatory powers and constitutes a taking of Monsanto's property. If Congress desires to exercise its power of eminent domain, which it has done in this case, and such power must be exercised

[4] The Supreme Court's opinions in *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427 (1919) and *National Fertilizer Association* v. *Bradley*, 301 U.S. 178 (1937), which dealt with the constitutionality of the government's police power to require proper labeling, are inapposite because labeling is provided with the products and the EPA has already determined the products safe and effective.

in light of the due process protections afforded by the Fifth Amendment. *Louisville Joint Stock Land Bank* v. *Radford*, 295 U.S. 555, 589 (1935).

The next issue raised is whether the compulsory binding arbitration scheme envisioned by § 3(c)(1)(D)(ii) is adequate to compensate Monsanto for the property taken by operation of FIFRA. Under the arbitration scheme of § 3(c)(1)(D)(ii) Monsanto is forced to either conclude a compensation agreement with a "me-too" applicant or take its chances with binding arbitration. Monsanto's failure to either reach an agreement with a "me-too" applicant or to submit to arbitration forfeits Monsanto's right to compensation and its property.

The Court initially notes that judicial review of an arbitrator's decision (Federal Mediation and Conciliation Service) is all but denied in except a few cases involving fraud. Equally important is the absence of a formula of a guidance on the evaluation of data for compensation purposes.

The Court finds the arbitration provision of § 3 arbitrary and vague. Not only are the arbitrators given no guidance as to the factors which make up just compensation, but judicial review of an arbitrator's decision, which may result in a confiscatory taking, is foreclosed. All of this is done without Monsanto's assent, *see N.L.R.B.* v. *Jones & Laughlin Steel Corp.*, 301 U.S. 1, 45 (1937).

In the Court's view, the arbitration scheme does not afford Monsanto just compensation and constitutes a denial of due process in violation of the Fifth Amendment. *See Baltimore & O.R.R.* v. *U.S.*, 298 U.S. 349, 357, 363, 368 (1936). The arbitration scheme also delegates judicial power to determine property rights disputes without the necessary prerequisites of Arti-

cle 3 of the Constitution. *See U.S.* v. *Security Industrial Bank*, 103 S.Ct. 407 (1982); *Northern Pipeline Const. Co.* v. *Marathon Pipeline Co.*, 102 S.Ct. 2858 (1982).

The final issue presented is whether the Tucker Act is available to provide Monsanto with adequate compensation for the taking of Monsanto's property rights. The Court's initial inquiry focuses on "not whether the (challenged statute) expresses an affirmative showing of congressional intent to permit recourse to the Tucker Act remedy" but rather whether Congress has "withdrawn the Tucker Act grant of jurisdiction to the Court of Claims to hear a suit involving the (challenged statute) founded upon . . . the Constitution." *Regional Rail Reorganization Cases*, 419 U.S. 102, 126 (1974). In the *Rail Act Cases*, the court analyzed the relevant acts and determined the Tucker Act remedy was available. Crucial to the court's analysis was the court's belief that the money allocated under the Act to provide compensation was intended to satisfy the constitutional standard of just compensation.

A fair reading of FIFRA indicates that the "benefits" (compensation and exclusive use) afforded by § 3 were intended to be the sole compensation for any taking effectuated by §§ 3(c)(1)(D) and 10. The compensation scheme set up by FIFRA rests on the theory that since the date of the original submitter is utilized for the private benefit of a competitor—rather than the United States—then the competitor should pay the original data submitter. No monies were allocated by the government to insure that adequate compensation would occur. It is clear that this scheme purportedly acts to completely compensate Monsanto for property taken immediately by the *de*

facto exercise of eminent domain accomplished by operation of FIFRA. *See Rail Cases*, 419 U.S. at 149-50 (cautioning that it might be inconsistent to suppose that a Tucker Act suit would lie for the *entire* value, in *cash*, of rail properties).

The Court finds that the Tucker Act remedy is not available to Monsanto for the deprivation caused by §§ 3 and 10 of FIFRA. The case at bar concerns an immediate taking of Monsanto's property as of the passage of the amendments to FIFRA on September 30, 1978. The compensation scheme, as presently embodied in § 3(c)(1)(D)(ii) is vague and uncertain and in effect provides Monsanto with no compensation whatsoever. To suppose that Monsanto would have to endlessly petition the Court of Claims every time the EPA uses or discloses its property is contrary to the purposes of the Tucker Act which is intended to award a sum of money to remedy a wrong in whole and with finality. Moreover, the Court of Claims cannot provide the necessary declaratory and injunctive relief which Monsanto must have.

The Court is aware that its decision is contrary to that of a number of other federal courts. *See e.g.*, *Mobay Chemical Co.* v. *Costle*, 519 F.Supp. 252 (W.D. Pa. 1981), *aff'd sub nom Mobay Chemical Co.* v. *Gorsuch*, 682 F.2d 419 (3rd Cir.), *cert. denied* 103 S.Ct. 343 (1982); *Penwalt Corp.* v. *EPA*, No. 80-2400 (E.D. Pa., July 17, 1981), *aff'd Mobay, supra; Chevron Chemical Co.* v. *Costle*, 499 F.Supp. 732 and 499 F.Supp. 755 (D. Del. 1980), *aff'd* 641 F.2d 104 (3rd Cir), *cert. denied* 452 U.S. 961 (1981); *Petrolite Corp.* v. *EPA*, 519 F.Supp. 966 (D.D.C. 1981). The Court deviates from these decisions because, in most of the above cited decisions, the courts summarily found that a property right did

not exist in data similar to that of Monsanto and, therefore, the courts necessarily did not analyze the 1978 amendments to FIFRA in their entirety. After reviewing the operation of FIFRA and its impact upon Monsanto's protected property rights, the Court is convinced that Congress exceeded its regulatory authority and violated the Fifth Amendment of the United States Constitution when in 1978 it amended §§ 3(c)(1)(D) and 3(c)(2)(A) and 10(b) and 10(d) of FIFRA.

Dated this 19th day of April, 1983.

/s/ H. Kenneth Wangelin
H. KENNETH WANGELIN
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, DEFENDANT

[Filed Apr. 9, 1983]

NUNC PRO TUNC ORDER

IT IS HEREBY ORDERED that page 39, lines 12 through 13 of the Court's Memorandum Opinion filed April 10, 1983 shall read as follows:

> contrary, the trial record amply demonstrates that competition in the pesticide industry is healthy and vibrant.

Dated this 9th day of May, 1983.

/s/ H. Kenneth Wangelin
H. KENNETH WANGELIN
United States District Judge

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, DEFENDANT

[Filed Apr. 12, 1983]

JUDGMENT

After a trial on the merits, wherein the Court carefully considered the evidence presented, the legal arguments proffered by the parties and the applicable law,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that §§ 3(c)(1)(D), 3(c)(2)(A), 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, 7 U.S.C. § 136 *et seq.*, are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, § 8, Clause 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto;

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby

PERMANENTLY ENJOINED from the implementation and enforcement, in any manner, directly or indirectly, of §§ 3(c)(1)(D), 3(c)(2)(A), and 10(b) and 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978; and

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that § 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, does not authorize the defendant to use or consider in support of another's application for registration any of plaintiff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by defendant without plaintiff's express written permission is unlawful; and

IT IS FURTHER ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby PERMANENTLY ENJOINED from any use or consideration for or disclosure to any other person of any of plaintiff's information, research and test data, whenever submitted to defendant or his predecessors, unless defendant shall have first obtained plaintiff's express written permission.

IT IS FURTHER ORDERED that a Memorandum Opinion detailing the findings of fact and conclusions of law in support of this Judgment shall issue within six (6) days of this Judgment.

Dated this 12th day of April, 1983.

/s/ H. Kenneth Wangelin
H. KENNETH WANGELIN
United States District Judge

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 79-366 C (1)

MONSANTO COMPANY, PLAINTIFF

vs.

ACTING ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, DEFENDANT

[Filed May 9, 1983]

AMENDED JUDGMENT

After a trial on the merits, the parties' filing of motions to stay and amend the Court's Judgment (which the Court treated as motions for a new trial),

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that §3 (c) (1) (D), the last sentence of § 3(c) (2) (a), § 10(b) and § 10(d) of the Federal Insecticide, Fungicide and Rodenticide Act, (hereinafter FIFRA) as amended by the Federal Pesticide Act of 1978, 7 U.S.C. § 136 *et seq.*, are unconstitutional and unlawful and that they are beyond any power conferred by Congress by Article I, § 8, Clause 3 of the Constitution of the United States and are in violation of the Fifth Amendment thereto; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby

PERMANENTLY ENJOINED from the implementation and enforcement, in any manner, directly or indirectly, of § 3(c)(1)(D), the last sentence of § 3(c)(2)(A), § 10(b) and § 10(d) of FIFRA, as amended by the Federal Pesticide Act of 1978; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that § 3(c)(1)(D) of FIFRA, as amended by the Federal Pesticide Act of 1978, does not authorize the defendant to use or consider in support of another's application for registration any of plaintiff's information, research and test data submitted prior to January 1, 1970, and such use and consideration thereof by defendant without plaintiff's express written permission is unlawful; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that defendant, his officers, agents, employees and representatives be and they are hereby PERMANENTLY ENJOINED from any use or consideration for or disclosure to any other person, other than to representatives of other agencies or offices of the United States Government including the Committees or Houses of the United States Congress, of plaintiff's information, research and test data, whenever submitted to defendant or his predecessors, unless defendant shall have first obtained plaintiff's express written permission; and

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that none of the aforesaid prevents the defendant from approving applications for pesticide registrations as permitted under §§ 3(c)(5) and 3(c)(7) of FIFRA in cases where the applicant has submitted to EPA, and relied solely upon, his own data to support his application for registration; provided that any applicant for registration must either

submit its own data, or cite its own previously submitted data, or cite data that appears in the public literature or cite the previously submitted data of another person with the prior written permission of such other person, and further that EPA is precluded from considering or using any other data in support of any application for registration.

Dated this 9th day of May, 1983.

/s/ H. Kenneth Wangelin
H. KENNETH WANGELIN
United States District Judge

APPENDIX D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

No. 79-0366-C (0)
(Judge Wangelin)

MONSANTO COMPANY, PLAINTIFF

v.

LEE VERSTANDIG, Acting Administrator,
United States Environmental Protection Agency,
DEFENDANT

[Filed May 10, 1983]

NOTICE OF APPEAL TO THE
UNITED STATES SUPREME COURT

Notice is hereby given that defendant, the Acting Administrator of the United States Environmental Protection Agency, appeals to the United States Supreme Court from the final judgment entered in this action on April 12, 1983, as amended by the judgment entered on May 9, 1983. This appeal is taken pursuant to 28 U.S.C. §§ 1252, 2101.

Respectfully submitted,

ROSANNE MAYER
Attorney, Department of Justice
Environmental Defense Section
Ben Franklin Station
P.O. Box 7415
Washington, D.C. 20044

THOMAS E. DITTMEIER
United States Attorney

/s/ Joseph B. Moore
JOSEPH B. MOORE
Assistant United States Attorney
Room 414, 1114 Market Street
St. Louis, Missouri 63101
314-425-4200, ext. 21

CERTIFICATE OF SERVICE

Copy of the above and foregoing mailed to Kenneth Heineman, Coburn, Croft, One Mercantile Center, Suite 2900, St. Louis, Missouri, Gary Dyer, Lathrop Koontz, et al., 2600 Mutual Benefit Life Bldg., 2345 Grand Ave., Kansas City, MO 64108, and W. Wayne Withers, Monsanto Agricultural Products Co., 800 N. Lindbergh Blvd., St. Louis, MO 63166, this 10th day of May, 1983.

/s/ J. Moore

APPENDIX E

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the Constitution provides in pertinent part:

> No person shall be * * * deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

The relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (& Supp. V) 136 *et seq.*, as amended in 1978, provide:

* * * * *

§ 136a(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

* * * * *

(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submit-

ted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitted, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide: *Provided*, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of

delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to reveiw any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The

parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to

respond. If a registration is denied or cancelled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;

(E) the complete formula of the pesticide; and

(F) a request that the pesticide be classified for general use, for restricted use, or for both.

(2)(A) Data in support of registration

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time

for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

§ 136h. Protection of trade secrets and other information

* * * * * *

(b) Disclosure

Notwithstanding any other provision of this subchapter and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this subchapter, information relating to formulas of products acquired by authorization of this subchapter may be

revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

* * * * *

(d) Limitations

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: *Provided*, That the use of such data for any registration purpose shall be governed by section 136a of this title: *Provided further*, That this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes.

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

(3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: *Provided*, That where the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may obtain disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not re-

quired to protect against an unreasonable risk of injury to health of the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

(e) Disclosure to contractors

Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this subchapter and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

(f) Penalty for disclosure by federal employees

(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained posesssion of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $10,000 or imprisoned for

not more than one year, or both. Section 1905 of title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this subchapter. Nothing in this subchapter shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.

(g) Disclosure to foreign and multinational pesticide producers

(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this subchapter to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on

the availability of information contained elsewhere in this subchapter, which information is relevant to a determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.

(3) Section 1001 of title 18 shall apply to any affirmation made under paragraph (1) of this subsection.

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